

Using Business Intelligence Tools to Support Medical Validation of Laboratory Tests

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Abstract. Modern clinical laboratories have to confirm that the procedures used for specific tests are reliable and valid. There are several sources of errors and interferences that can invalidate the results. Medical validation refers to the plausibility check of the test results. Implausible results indicate that something might went wrong with a sample retrieved from the patient, e.g., the blood sample got contaminated with another fluid, which requires re-examination. Here, we describe how an integrated R-based business intelligence (BI) tool can be developed that increase the efficiency of the medical validation at the Institute of Clinical Chemistry (ICC) of the University Hospital Zurich. A BI software environment allowed us to digitalize steps in the validation process that were manually done in Excel worksheets, e.g., importing the data, calculating percentiles, and producing graphical outputs.

Keywords. Clinical validation; delta check; extreme value analysis; business intelligence; R

1. Introduction

It is indispensable for modern clinical laboratories to confirm that the procedures and methods used for specific tests are reliable and valid. There are several sources of errors and interferences that can invalidate the results. One important distinction in this regard is between technical and medical sources [1,2]. The former one relates to the quality of laboratory devices and instruments used, e.g., purity of chemicals or adequacy of materials. Whenever a test is introduced, changed or used in a new context, technical validation should be triggered. There are several guidelines and quality standards for ensuring technical validity [3]. Medical validation, on the other hand, refers to the plausibility of the test results. Assuming technical validity, implausible results indicate that something went wrong with a sample retrieved from the patient, e.g., a blood sample was contaminated with another fluid, which requires re-examination.

Medical validation consists of two parts: transversal and longitudinal assessments, addressing the plausibility of results with respect to a population or to an individual [4]. Transversal assessments can be based on all patients of a hospital, for which the same test procedure was executed. This allows to set limits on the values to be expected from

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a test, for example in the form “the cardiac troponin values on our devices for 99% of all our patients in the last year range between 0.04 ng/L and 100 ng/L”. This type of validation is often called extreme value analysis. For longitudinal assessments, several measurements of the same parameter for the same patient are compared with each other. Plausibility in this context defines whether delta changes are within sensible limits or not. The phrase used for such assessments is “delta check”.

Our working environment was the Institute of Clinical Chemistry (ICC) of Zurich University Hospital (USZ). Several tools were in use to calculate the percentiles and produce graphical outputs, mainly Excel based spreadsheets with added functionality. The workplace of the scientific staff responsible for the validation was separated from the laboratory premises. This physical distance creates a clear separation between the day-to-day business (laboratory examinations) and the validation process, allowing high flexibility in the adaptations of workflows. In this context, we were approached to tackle the question of whether it is possible to increase the efficiency of the medical validation at ICC by business intelligence tools.

2. Methods

2.1 Review of the literature

Our literature research was based on the PubMed and Cochrane Library databases. The focus was on studies that use business intelligence and/or the statistical environment R for delta check procedures and extreme value analysis. Keywords were identified in particular through preliminary discussions with stakeholders. These were then entered into the database mask in various combinations:

- ("medical validation") AND "r statistics"
- ("medical validation") AND "business intelligence"
- ("delta check") OR "r statistics"
- ("delta check") OR "business intelligence"
- ("extreme value analysis") AND "r statistics"
- ("extreme value analysis ") AND "business intelligence"

2.2 Approaches and tools considered

For deriving requirements, we used user stories as well as uses case diagrams. The former technique stems from the agile development framework Scrum [5]. A user story informally describes features of a software system from the perspective of the user; hence, it focuses on what the user needs instead of what the system should deliver. One example in our context: User A (who) wants to calculate percentiles (what) to decide whether validation is necessary (goal). This made it possible to gain a better mutual understanding of the system [6]. Use Cases in contrast describe how the system will act. The creation of a use case was intended to concretize the functional and non-functional requirements of the system and to illustrate the interaction between user and system.

Based on the results of our requirement analysis, we developed a business intelligence application (BIA) using on Microsoft Power BI (Desktop version August 2018) and R (3.5.2). For user-system interactions and visualization, we used an

interactive HTML widget in order to improve the user experience. To implement this widget, additional R packages are required, namely *ggplot2* and *plotly*. The availability of Microsoft Power BI at the ICC and its connection to hospital wide data warehouse made it a natural choice as BI environment.

3. Results

The results of our literature research demonstrated, albeit various methodological improvements were proposed (e.g. see [7]), that there is a gap between the availability of business intelligence tools and their usage for supporting the medical validation workflow in laboratories. In addition, information on the use of expert systems within the clinical laboratory [8], on automated validation for clinical laboratory test results [9], and on the usage of Microsoft Power BI and R for business intelligence applications could be collected [10, 11].

Together with our stakeholders, we defined different workflows to be supported in shape of user stories:

- “As a research assistant, I need up-to-date clinical laboratory test data in order to perform medical validation.”
- “As a research associate, I want graphical visualizations to give me a first idea of the data shape.”
- “As a research associate, I need to calculate percentiles in order to decide whether validation is necessary.”
- “As a research assistant, I need an intuitive user interface to get around quickly.”
- “As a research assistant, I need a user manual so that I can inform myself about the individual functions of the application.”

Discussing these user stories and use case diagrams developed in the requirement analysis phase allowed us to identify following functional requirements:

- i. Interfacing to stored clinical data; in our case to clinical data in the data warehouse of the hospital,
- ii. Support for two separate validation workflows: extreme value analysis and delta check,
- iii. Possibility to specify any time span,
- iv. Filter functions to specify age ranges and sex of the population,
- v. Summary statistics and interactive visualizations (e.g., histograms)
- vi. Automated computation of several percentiles (.01, .025, .05, .95, .975, .99)

Implementing these requirements with a business intelligence software environment allowed us to digitize steps in the validation process that were previously done manually in Excel worksheets; especially, importing the data, calculating percentiles, and producing graphical outputs. In first validations of the tool, the average time for each validation was around two minutes in contrast to 30 minutes with the old solution. Due to the flexibility of the validation workflow, further adaptations can be realized rather quickly. The user interface for the extreme analysis uses filters for

selecting the population on the left panel of the page. The user can specify the laboratory test, the time period, sex and the age range. On the main panel, the results are interactively updated according to the specifications; the core result elements are an interactive histogram, the number of examinations considered, and percentiles. The user interface for the delta check was structured in the same way (see Figure 1). In addition, we included buttons for absolute (default) and relative values (the difference divided by the first value).



Figure 1: The Delta Check page of our application with filters on the left panel and results on the main panel.

Discussion

We were able to increase the efficiency of the medical validation process at the ICC by automating many time-consuming validation steps that were performed manually before. Due to the automation, reduced error rates can be expected. One important advantage of using an R-based BI tool is related to the out-of-the-box functionalities it provides, e.g., for data import, for interactive visualizations and for statistical summaries. The functional requirements list in the result section describes key requirements that typically arise in such contexts.

Development took place on a development environment. Before moving to the production environment, a few hurdles have to be considered. First, there are different Power BI versions: we used Power BI Service for development, but for security reasons (if cloud solutions are not permitted) Power BI Reporting Services should be used, which might require license update. Second, HTML widgets in one Power BI version might not work in another. Third, the graphics integrated into Power BI via R can only deal with data frames having at maximum 150,000 rows [12].

Using R comes with a lot of functionality, stemming from an open research community [13,14], that can be used for advanced statistics and machine learning (ML). Although Python gains high attention for data science applications, for visualization

and scientific-based data analysis, R is still one of the most widespread and dynamic programming environments. The use of ML in a future version could lead to an even faster validation process. The whole process of plausibility checks based on different percentiles and patient characteristics can be automated and trained by a neural network, which can be enabled to integrate many different kinds of information. The keras-package in R [15] is highly suitable for that purpose and its integration will be our next goal.

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